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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,366	06/09/2000	Narayan Baidya	421452000100	3103

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/24/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/591,366

Applicant(s)
Baidya et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/19/02, 6/28/02, and 10/18/02
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 49-68 is/are pending in the application.
- 4a) Of the above, claim(s) 23 is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 49-68 is/are rejected.
- 7) ☒ Claim(s) 24-48 have been canceled. ~~is/are objected to~~
- 8) ☒ Claims 1-23 and 49-68 are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) (3 sheets)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Applicants' arguments; filed 3/19/02, 6/28/02, and 10/18/02; have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The elected claims are only directed to arrays whereas the title encompasses arrays as well as a method of preparing an array of polynucleotide probes.

NEW MATTER

Claims 49-68 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support for the newly submitted claim 49 was cited as being replete in the specification as well as in Examples 1 and 2. Consideration of the specification as well as Examples 1 and 2 has failed to reveal the limitation presented in claim 49 directed to each polynucleotide probe being "complementary to

only the 3' untranslated sequence". This limitation directed to "only the 3' untranslated region" is thus NEW MATTER. Specifically Examples 1 and 2 cite STS probes but without recognizing with written description that such probes are meant to "only" contain 3' untranslated sequence. Such Examples may describe a set of probes and their usage but as such are specific for that set only unless a generic "only 3' untranslated sequence" concept is additionally set forth to support such a generic limitation as now in newly submitted claim 49. Claims dependent from claim 49 directly or indirectly also contain this limitation due to their dependence.

LACK OF ENABLEMENT

Claim 18 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented,

(3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is maintained only regarding instant claim 18. It is acknowledged that many specific sites on chromosomes with corresponding sequence segments are known in the art. Thus, claims such as instant claim 1, drawn to arrays wherein the probes present therein are generically described without a specific sequence are deemed enabled by such generic chromosomal site specific sequences in the art. Claim 18, however, is not directed to generic sequences but rather are specific to sequences defined by the primer pairs therein cited in the claim. In order to utilize such specific sequences in array usage, the corresponding specific information as to each of their "defined chromosomal location" is required in order to practice this phrase in the last two lines of claim 1, from which claim 18 depends. This information regarding the "defined chromosomal location" for each probe as characterized in claim 18 is

therefore essential material for the use of said claim 18 arrays. It is noted that essential material, even if available in the art, cannot be incorporated by reference to printed publications, such as Genbank listings, EMBL listings, etc. as argued by applicants. See the following paragraph regarding improper incorporation by reference to printed publications.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

PRIOR ART BASED REJECTIONS

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant

is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-7, 9-17, 19-22, 49-55, and 57-68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Duggan et al. [Nat. Genetics 21(Suppl.):10(1999)] in view of Schena et al. [Science 270(5235):467(1995)], taken further in view of Wilcox et al. [NAR 19(8):1837(1991)], with Genbank Accession number summaries for H36236 (441 bases in length), U36594 (359 bases in length), T45783 (385 bases in length), U36595 (298 bases in length), T04477 (400 bases in length), R87034 (415 bases in length), T14152 (363 bases in length), T22720 (332 bases in length), U36596 (293 bases in length), J04185 (1863 bases in length), and Z18205 (235 bases in length) as cited within Schena et al.

This rejection is maintained and reiterated from the previous office action, mailed 10/9/01, but further expanded regarding the STS type probes which are available for usage as hybridization probes. Both Schena et al. as well as Wilcox et al. describe PCR amplified hybridization probes of a variety of lengths. Schena et al. on page 467, bridging paragraph between the first and second columns and the first full paragraph in the second column, describes the usage of ESTs prepared from cDNAs via PCR. The cDNA lengths are therein described as averaging approximately 1.0 kb, but without specifying thereby the PCR

amplified probe lengths as prepared therefrom. A set of actual PCR amplified probes are described, however, in Table 1 of Schena et al. on page 469. Consideration of a random selection of EST probes from Table 1, well known to be subsegments of cDNAs, reveals a variety of lengths. The random selection is now attached to this Office Action with descriptions of them as Genbank summaries of certain random selections listed with Accession numbers of H36236 (441 bases in length), U36594 (359 bases in length), T45783 (385 bases in length), U36595 (298 bases in length), T04477 (400 bases in length), R87034 (415 bases in length), T14152 (363 bases in length), T22720 (332 bases in length), U36596 (293 bases in length), J04185 (1863 bases in length), and Z18205 (235 bases in length). Consideration of Schena et al. reveals that several arrays are described for use with various analyses as desired. Similarly, Wilcox et al. describes various length probes including specifically PCR product probes as prepared as described on page 1838, first column, in the section entitled "Selection of PCR Primers" therein described as 50-350 bp in length. A typical STS probe is shown on page 1841, Figure 5 with a length of 77 bases. In summary, applicants argue that the combination of references do not describe short probes for hybridization studies. In response the above citations included further Genbank data clearly describe the range of probe sizes for such hybridization analyses

to include lengths, even to only 77 bases in length thus clearly suggesting array practice in the range of the instant claims regarding probe length. Since hybridization arrays of such probes are described and utilized as noted in the references, especially Schena et al. these descriptions also support a reasonable expectation of success for such hybridization practice. Applicants further argue that the references do not "only" target 3'-untranslated sequence regions. In response this limitation is not seen in the instant claims, which are inclusive of such 3'-untranslated regions but are not limited to "only" containing such sequences. Even if the claims were to be limited to "only" containing such 3'-untranslated regions, the reference by Wilcox et al. clearly motivates and suggests the successful usage of probes of this type as noted in the title as well as the entirety of Wilcox et al.

Claims 1-17, 19-22, and 49-68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Duggan et al. [Nat. Genetics 21(Suppl.):10(1999)] in view of Schena et al. [Science 270(5235):467(1995)], taken further in view of Wilcox et al. [NAR 19(8):1837(1991)], and taken further in view of Fodor et al. (P/N 5,510,270), with Genbank Accession number summaries for H36236 (441 bases in length), U36594 (359 bases in length), T45783 (385 bases in length), U36595 (298 bases in length), T04477 (400 bases in length), R87034 (415 bases in length), T14152 (363 bases in

length), T22720 (332 bases in length), U36596 (293 bases in length), J04185 (1863 bases in length), and Z18205 (235 bases in length) as cited within Schena et al.

This rejection is maintained and reiterated from the previous office action, mailed 10/9/01, but further expanded regarding the STS type probes which are available for usage as hybridization probes. This rejection is not argued further than has already been responded to above and is equally non-responsive here.

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 20, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER